AUG 1 2001

K010500

510(k) SUMMARY
LAB-InterLink, Inc.'s Automated WorkCell Control Software

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

LAB-InterLink, Inc.
1011 South Saddle Creek Road
Omaha, Nebraska 68106
Phone: (402) 595-3767 Ext. 2861
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Contact Person: Deborah S. Kipp

Date Prepared: February 20, 2001

Name of Device and Name/Address of Sponsor

Automated WorkCell Control Software

Common or Usual Name

AWCC Lab automation software

Classification Name

Accessory to third party analyzers

Predicate Devices

Third party analyzers, including as examples only:

- Ortho Clinical Diagnostic's ("OCD") Vitros 950 AT analyzer and Vitros 250 AT automated analyzer (K962919);
- Bayer Diagnostic's Immuno-1 analyzer (K983345, K962125) and ACS:180/Advia Centaur analyzer (K902336);

- Medical Laboratory Automation's Electra 1600C system (K931206);
- Abbott Diagnostics' Cell-Dyn 4000 automated hematology analyzer (K961439) and Architect i2000 System; and
- DPC Cirrus' Immulite 2000 Automated Immunoassay Analyzer (K970227).

Intended Use

The AWCC software is an accessory to analyzer instruments, including for example discrete photometric chemistry analyzers, coagulation timers, fluorometers, and/or cell counters. These analyzers are intended for use in conjunction with certain materials to measure a variety of analytes, to determine the onset of clot formation for in vitro coagulation studies, to identify and classify one or more of the formed elements of the blood, and/or other indications for which third party analyzers are legally marketed.

Technological Characteristics and Substantial Equivalence

Each of the analyzer products with which the AWCC may be used, including fluorometers, photometric chemistry analyzers, coagulation timers, and differential cell counters, are analytical instruments intended for use in the analysis of specimens with in vitro diagnostic methods or procedures to determine relevant clinical characteristics of the sample. The AWCC product, as an accessory to the analyzers, does not change, expand, or limit the intended use of each analyzer product. Rather, the AWCC software provides a method for automatically providing information to the analyzer that would otherwise be entered manually into the analyzer. The AWCC does not alter the information, provide different information, or provide command or control functions for the analyzer. Thus, each analyzer's intended use with the AWCC is identical to its intended use without the AWCC.

Each of the analyzers described above as examples of the analyzers with which the AWCC family interacts operate on the principle that human specimens contain analytes that can be measured using fluorometric reagents, photometric reagents, or by determination of coagulation time,

and/or cells that may be enumerated. The technological method by which each analyzer interacts with specimens is inherent to the analyzer and analyte/characteristic being assessed.

The AWCC products do not interact with or alter each analyzer's method of analyzing specimens or the technological characteristics of the analytical methods. Rather, the AWCC automatically provides information about specimen identity and analytical methods that is routinely entered manually into each analyzer. Thus, use of the AWCC as an accessory to each analyzer does not alter the principles of operation or technological characteristics of the analyzer.

Because each AWCC software product interacts with 510(k) cleared or 510(k) exempt analyzers in a way that does not change the intended use, indications, principles of operation or technological characteristics of the original device, the AWCCs are accessories to the analyzers that are substantially equivalent to the predicate devices.

Performance Data

Performance testing performed for each AWCC-third party analyzer installation includes the analysis of multiple individual analytes tested independently using the third party analyzer with and without the AWCC interface. This analysis demonstrates for each AWCC software product that use of the AWCC with the analyzer produces results that are significantly correlated ($r \geq 0.92$) to the results obtained with the analyzer alone and that the percent difference between results is within the range of analyte inter-assay variability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 2001

Ms. Deborah S. Kipp
Quality Assurance Manager
LAB-InterLink, Inc.
1011 South Saddle Creek Road
Omaha, NE 68106

Re: 510(k) Number: K010500
Trade/Device Name: AWCC Software
Regulation Number: 864.5220, 864.5400, 862.2160, 862.2560
Regulatory Class: II
Product Code: GKZ, GKP, JJE, KHO
Dated: May 22, 2001
Received: May 23, 2001

Dear Ms. Kipp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 8
Indications for Use Statement

510(k) Number (if known): K010500

Device Name: AWCC Software

Indications for Use:

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Jean Cooper
(Division Sign-Off)
Division of Clinical Labor
510(k) Number K010500

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)